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(n=161, 46.3%). Toxicity was the most common reason for dose hold (n=94, 58.4%); 78 subsequently restarted AXI+PEM at their current (n=19) or a reduced (n=59) dose. Mean (SD) time to dose hold as first TM was 61.1 (55.9) days (n=39, 11.2%). Toxicity was the reason for dose hold among 24 (61.5%) patients; of these, 23 restarted AXI+PEM at a reduced dose. Discontinuation was the first TM in 91 (26.2%) patients; mean (SD) time to discontinuation was 97.7 (89.7) days among them. Discontinuation was due to toxicity in 39 (42.9%) patients and progression in 29 (31.9%) patients; cabozantinib was the most common treatment (n=31, 8.9%) after discontinuation.

Conclusions: Real world demographic and clinical characteristics were generally consistent with randomized controlled trials. Dose holds, changes and discontinuation were driven by toxicity; this analysis highlights opportunities to engage in targeted therapy management interventions to address treatment toxicity.

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112P Immunogenicity of the mRNA-1273 SARS-CoV-2 vaccine in cancer patients receiving immunotherapy agents

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Background: Little is known about the influence of different anticancer therapies in the immunogenicity, efficacy, and safety of SARS-CoV-2 vaccines. Particularly, Immunotherapy could increase the rate of response to COVID-19 vaccines, counteracting cancer immunosuppression and restoring T-cell competence.

Methods: We conducted an observational study to assess the immunogenicity of mRNA-1273 SARS-CoV-2 vaccination in patients with solid tumours treated with immunotherapy. Blood samples were collected to analyse the humoral (specific anti-spike IgG) and cellular response (IFN- γ producing CD4+ and CD8+ T-cells after stimulation with structural viral proteins) at baseline (BL), after the first vaccine dose (1D) and after the second vaccine dose (2D). Patients with previous COVID-19 or positive serology were excluded.

Results: The characteristics of the 25 patients included were: median age 65.9 years (IQR 56.2 – 72.8); 48% female; 28% with genitourinary tumours, 20% melanoma, 16% lung cancer and 36% with other tumours; 92% stage IV; treatment with anti-PD1 in 64%, with anti-PDL1 in 24% and with a combination of anti-CTLA4 plus anti-PD1/PDL1 in 12%. Median anti-spike (S) IgG titres were 0.95 AU/ml (IQR 0.3 – 23.3) at BL, 544.2 (IQR 239 – 995.5) after 1D and 14238.1 (IQR 8570.3 – 28717.9) after 2D. Humoral response (cut-off point = 50 AU/ml) was significantly improved reaching 94.4% after 1D and 100% after 2D (p<0.001). Of note, cellular response at BL was found in 20% and 25% for CD4+ and CD8+ anti-S T-cells respectively, suggesting cross-reactivity. After 2D of vaccine, CD4+ and CD8+ T-cell response was observed in 58.8% (p=0.01) and 64.7% (p=0.03), respectively. Nevertheless, after excluding patients with previous positive serology or/and cross-reactive cellular response, only 41.7% and 58.3% had CD4+ or CD8+ anti-S T-cell response, respectively. Overall, there were no severe reactions to the vaccine.

Conclusions: Our study shows that patients with solid tumours treated with immunotherapy agents achieve a robust humoral response but, contrary to what was expected, poor cellular response against SARS-CoV-2 after full vaccination. Alternative treatment strategies are needed to improve the immunogenicity of SARS-CoV2 vaccines for these patients.

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113P Health outcomes and budget impact projection of the anti-PD-(L)1 class in cancer care in Portugal

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Background: Immunotherapies targeting programmed death-1 and its ligand (PD-(L)1) revolutionized the therapeutic landscape in cancer. However, the rapidly growing number of patients eligible for these drugs challenges the affordability of health systems. This study aimed to estimate the health and budget impact of the anti-PD-(L)1 class in Portugal and inform current discussions.

Methods: The study was based on the Health Impact Projection (HIP) model, which compares clinical outcomes (life years, progression-free survival [PFS] years, and patient quality-adjusted life years [QALY] gained and adverse events [AEs] occurred) and economic impact (direct and indirect costs) in a world where cancer patients are treated with standard-of-care (SOC; reference scenario) versus a mix of SOC and anti-PD-(L)1 (new scenario) in a 3-year time horizon (2021–2023). Six cancer types were included: adjuvant and metastatic melanoma, non-small cell lung cancer (first and second line), metastatic triple-negative breast cancer, head and neck cancer, urothelial carcinoma, and renal cell carcinoma. Model inputs were based on publicly available data, literature data, and expert opinion.

Results: The model estimated that in 2021–2023, 12,890 patients would be diagnosed and treated with anti-PD-(L)1, realising a gain of 4,787 life years (+23% of relative gains), 6,901 PFS years (+98%), and 4,214 QALYs (+30%) and avoiding 399 AEs (+4%). The class had a projected average annual impact of \approx €108 million in the 3 years and a projected share of 20% of cancer care expenditure and 0.6% of total healthcare expenditure in 2021. Although higher disease management and administration costs are expected due to patients living longer with anti-PD-(L)1, and drug acquisition costs are considerable, some of it is offset by a reduction in end-of-life costs (average €611,092/year) and in costs of patient productivity lost to cancer (average €9,128,142/year).

Conclusions: This study highlights the clinical benefit of anti-PD-(L)1 for cancer patients and provides valuable insights to policymakers on their economic impact on cancer care costs and healthcare system budget, contributing to decision-making and budget planning.

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